Remarks

Upon entry of the amendments submitted herein, claims 23-82 will be pending. Claims 1-22 have been canceled previously or herein without prejudice or disclaimer. Applicants reserve the right to pursue subject matter encompassed by all canceled claims in one or more continuation or divisional applications. No new matter has been added.

The Examiner has returned form PTO/SB/08 and indicated that the references cited therein have not been considered because the references have apparently been lost. *See*, Paper No. 92004, page 3, item 5. In compliance with the Examiner's invitation, Applicants resubmit herewith a copy of form PTO/SB/08 (5 pages; previously submitted on August 16, 2004) and copies of the previously submitted references AE-BJ. Applicants respectfully request consideration of the references (indicated by Examiner initialing the resubmitted copy of form PTO/SB/08). Since the above referenced Information Disclosure Statement and copies of references cited therein were originally submitted in compliance with 37 C.F.R. § 1.97(b), and since these documents were lost through no fault on the Applicants' part, no fee is believed due for resubmission of this Information Disclosure Statement or the references cited therein.

Withdrawn From Consideration

The Examiner has withdrawn claims 1, 19, 37-39, 54-56, 67-69, and 80-82 from consideration. *See*, Paper No. 92004, page 2, item 3. Applicants have canceled claims 1 and 19 previously or herein without prejudice or disclaimer.

Applicants have not canceled process claims 37-39, 54-56, 67-69, and 80-82 which were withdrawn from consideration by the Examiner. Applicants note that in light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ 2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. *See*, 1184 OG 86 (March 26, 1996). Specifically, the notice states, "in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim." *Id.* Thus, in the present application, upon

allowance of the pending product claims (previously restricted to Group III), Applicants respectfully request rejoinder of process claims 37-39, 54-56, 67-69, and 80-82.

Amendments to the Specification

A new title that is "clearly indicative of the invention *to which the claims are directed*" has been requested by the Examiner. *See*, Paper No. 92004, page 2, item 4. In respect of this request, Applicants have herein amended the title to read: "Antibodies to Fc Receptor-like V Polypeptides".

The Examiner has noted that "the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors." *See*, Paper No. 92004, page 10, item 17. Furthermore, the Examiner indicated that the word "muteins" is misspelled on page 41, in paragraph 0094, and requested correction thereof. *See id.* Applicants submit, however, that "muteins" is spelled properly at page 41, paragraph 0094. A "mutein" is a mutated protein and "muteins" is the desired word to have at this place in the specification. In accordance with the Examiner's request, Applicants will notify the Examiner and request correction of errors of which they become aware.

Objection to Claim 21

Claim 21 is objected to as being dependent upon non-elected claim 19. *See*, Paper No. 92004, page 3, item 6. Applicants have herein canceled claim 21 without prejudice or disclaimer. Accordingly, Applicants submit that the objection to claim 21 has been rendered moot.

Rejection under 35 U.S.C. § 101

Claims 21, 23-26, 40-53, 57-66, and 70-79 are rejected under 35 U.S.C. § 101 as allegedly "not supported by either a specific and substantial asserted utility or a well-established utility." *See*, Paper No. 92004, pages 3-6, item 8. Specifically, the Examiner alleges that the presently claimed antibodies lack utility because: (1) "the specification fails to provide sufficient objective evidence of *any* activity for [the] encoded protein"; (2) "there is no information pertaining to the significance of the percentage homology, e.g. whether there were any conserved motifs that would [have] led the artisan to accept the

protein's function"; and (3) "the specification does not disclose *any* diseases or conditions known to be associated with the FcR-V polypeptide, encoded by SEQ ID NO:10 or any conditions associated with altered levels (increase or decrease) of said polypeptide." *See id.* (emphasis added).

As an initial matter Applicants note that claim 21 has been canceled herein, without prejudice or disclaimer. Therefore, the rejection to this claim under 35 U.S.C. §101, first paragraph has been rendered moot.

With respect to the remaining rejected claims, Applicants respectfully disagree and traverse. Contrary to the Examiner's allegations, the specification does, in fact, disclose a specific and substantial asserted utility for FcR-V polypeptides and, consequently, a specific and substantial utility for the presently claimed antibodies that bind the FcR-V polypeptides. In particular, the specification teaches that, based *in part* on homology to the Fc-γ2 receptor, the FcR-V polypeptides are important in the regulation of the immune and hematopoietic systems and are "thought to function as an important trigger of complex immune defense responses including phagocytosis, antibody-dependent cellular cytotoxicity, and release of inflammatory mediators" and are thought to play a dominant role in type II hypersensitivity reactions. *See, e.g.,* page 16, paragraph 0032. Further, the specification teaches that the FcR-V polypeptides are useful for the diagnosis or treatment of specific immune system-related disorders, including

> immune-complex related inflammatory diseases such as rheumatoid arthritis, systemic lupus erythmatosis, autoimmune hemolytic anemia, thromboctyopenia and IgG- or IgE-mediated inflammation, anaphylaxis, allergy ....."

See, e.g., page 60, paragraph 0135. Therefore, the specification clearly asserts a specific biological role for the FcR-V polypeptides involving the regulation of the immune and hematopoietic systems (e.g., allergy and inflammation) and correlates this activity to a specific group of immune system-related disorders. As such, it logically follows that there is at least one patentable use for the antibodies of the present invention given the role of the FcR-V proteins in immune function.

Accordingly, where the specification discloses a biological activity (*e.g.*, regulation of the immune system), and reasonably correlates that activity to a disease condition (*e.g.*, rheumatoid arthritis), the specification has sufficiently identified a specific utility for the

invention. M.P.E.P. § 2107.01 at 2100-32 (emphasis added). In other words, so long as the correlation between the biological activity and the asserted use in a particular disease or condition is sufficient to convince one of skill in the art, then the specificity requirement of 35 U.S.C § 101 is satisfied. *See also, Fujikawa v. Wattanasin*, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996).

With regard to the Examiner's allegation that "there is no information pertaining to the significance of the percentage homology, e.g. whether there were any conserved motifs that would [have] led the artisan to accept the protein's function," Paper No. 92004, page 4. Applicants respectfully point out that the specification does indeed disclose significant conserved domains between the Fc-γ2 receptor and the FcR-V protein. Specifically, the specification discloses that the FcR-V protein of the present invention and the bovine Fc-γ2 receptor share "the following conserved domains: (a) the predicted extracellular domains which consists of about 90 amino acids; (b) the predicted transmembrane domains of about 21 amino acids; and (c) the intracytoplasmic domains of about 15 to 150 amino acids." *See, e.g.,* pages 4 and 5, paragraph 0012; page 19, paragraph 0038; and Figure 14. Furthermore, the specification discloses that the

> FcR-V [protein] and the Fc-γ2 receptor are also especially related in the Ig-like repeat elements of the extracellular domain. In general, the conservation of such Ig-like domains is a hallmark of FcRs. The FcR Ig-like domain is characterized by two main conserved structural amino acid sequences, each of which is centered around a cysteine residue (Raghavan, M. and Bjorkman, P.J. *Annu. Rev. Cell Dev.* 12:181-220; 1996) ... Each of the novel FcR molecules of the present invention characteristically contains either two or three of the above-mentioned repeat sequence pairs ... FcR-V contains three pairs of the Ig-like domains in its extracellular domain located around the three pairs [of] cytsteine residues located at positions 33 and 81, 139 and 179, and 228 and 279 of SEQ ID NO:10.

See, e.g., page 19, paragraph 0039. Therefore, not only does the specification disclose conserved sequences common to FcRs which are shared between FcR-V and Fc-γ2, the specification also references Raghavan *et al.*, which corroborates the asserted utilities of the FcR-V protein. *See,* Raghavan *et al.* (1996), entire document (previously submitted as reference AG with the Information Dislcosure Statement filed August 16, 2004 and resubmitted herewith)

Additionally, Applicants have submitted third party publications which *further corroborate* the specific and substantial utilities described in the specification. For example, the specific utility for the protein and/or antibody described in the specification is corroborated by the post-filing date reference Tedla *et al.*, PNAS, 100(3):1174-1179 (2003) (previously submitted as reference BJ with the Information Dislcosure Statement filed August 16, 2004 and resubmitted herewith). Tedla *et al.* discloses that leukocyte Ig-like receptor (LIR7) activates immunological and/or inflammatory responses such as the release of the proinflammatory cytokine IL-12, the release of the proinflammatory leukotriene C4, and the release of histamine, which are well known to play important roles in host responses to inflammation, allergic diseases and parasitic infections (*See*, Tedla *et al.* (2002), page 1174, first 2 columns).

Applicants include herewith the polypeptide sequence alignments of SEQ ID NO:10 and the LIR7 polypeptide sequence of Tedla *et al.*, (*See* Exhibit A attached). Comparison of the sequences reveals that the LIR7 amino acid sequence is identical to the FcR-V amino acid sequence at positions –15 to 450. Therefore, the LIR7 and FcR-V amino acid sequences have identical Ig-like domains characteristic of FcRs and also have identical short cytoplasmic domains and positively charged arginine residues within their transmembrane domains that are characteristic of activating LIRs. *See, e.g.,* specification page 19, paragraph 0039; Tedla *et al.,* page 1174. Accordingly, Tedla *et al.* corroborate that FcR-V polypeptides of the invention and thus, antibodies that bind FcR-V, are useful in treating and/or diagnosing disorders of the immune system, such as allergy and inflammation.

In view of the above evidence and explanations, Applicants submit that the presently claimed invention has at least one or more patentable utilities. Therefore, Applicants respectfully submit that the rejection of claims 23-26, 40-53, 57-66, and 70-79 under 35 U.S.C. §101 has been obviated and respectfully request that the rejection of the claims be reconsidered and withdrawn.

Rejection of claims 21, 23-26, 40-53, 57-66, and 70-79 under 35 U.S.C. § 112, first paragraph

Claims 21, 23-26, 40-53, 57-66, and 70-79 are rejected under 35 U.S.C. § 112, first paragraph, based upon a premise that "since the claimed invention is not supported by

either a specific and substantial, asserted utility or a well established utility for the reasons set forth in the rejection under 35 USC § 101 above, one skilled in the art clearly would not know how to use the claimed invention." *See*, Paper No. 92004, page 6, item 10.

Applicants respectfully disagree and traverse.

First, claim 21 has been canceled herein without prejudice or disclaimer. Therefore, the rejection of this claim has been rendered moot. Second, Applicants respectfully submit that, as explained above, claims 23-26, 40-53, 57-66, and 70-79 are supported by specific, substantial, and/or well-established utilities. Hence, in view of the present application's disclosure and the state of the art as of its earliest filing date, Applicants submit that a person having ordinary skill in the art would certainly know how to use the claimed invention. Accordingly, Applicants respectfully request the rejection of pending claims 23-26, 40-53, 57-66, and 70-79 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Rejection of Claims 57-66 and 70-79 under 35 U.S.C. § 112, first paragraph

Claims 57-66 and 70-79 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not [sufficiently] described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *See*, Paper No. 92004, page 6, item 12. In particular, it is asserted that the Applicants have not pointed out where support for claims 57-66 and 70-79 can be found in the specification. *See*, Paper No. 92004, page 6, item 12, second paragraph.

Applicants submit that the present specification does, in fact, provide sufficient written description for claims 57-66 and 70-79. First, Applicants note that the specification clearly describes FcR polypeptides as transmembrane domain containing cell surface molecules. *See*, for example, page 2, paragraph 0006; and, pages 8-11, paragraph 0017. Second, Applicants note that support for claims 57-66 and 70-79 can be found in the specification, for example, at pages 56-57, paragraphs 0124 and 0125 where it is described that cells expressing FcR-V proteins can be administered to an animal in order to induce the production of antibodies. Therefore, in view of the above cited support for claim 57-66 and 70-79 in the specification as filed, Applicants respectfully request the

rejection of these claims under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph based on the ATCC Deposit

The Examiner has requested an affidavit or declaration regarding the FcR-V cDNA deposit to overcome a rejection of claims 21, 40-53 and 70-79 under 35 U.S.C. § 112, first paragraph. *See,* Paper No. 92004, page 7, item 13. Additionally, the Examiner has stated that "amendment of the specification to disclose the date of the deposit and complete name and address of the depository is required." *See*, Paper No. 92004, page 7, item 13, last paragraph.

Preliminarily, claim 21 has been canceled herein without prejudice or disclaimer. Therefore, the rejection of this claim has been rendered moot.

Furthermore, Applicants respectfully point out that the specification, as set forth in 37 C.F.R. § 1.809 (d), describes at page 4, paragraph 0011 that ATCC Deposit No. 209100 was deposited on June 6, 1997 under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, Virginia 20110-2209, USA. Thus, the Examiner's request that the specification disclose the date of the deposit and complete name and address of the depository has been obviated.

However, in accordance with the Examiner's request for an affidavit or declaration regarding the FcR-V cDNA, the following declaration is respectfully submitted:

Availability of the Deposit

> Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on June 6, 1997, accepted by the ATCC, and given ATCC Accession Number 209100. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number

209100 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). The assignee of the present application has been notified of its responsibility to replace the deposited biological material should the deposited material be destroyed or rendered non-viable.

In view of the above affirmation and explanation, attested to by the signature (below) of the Attorney for the Applicants, it is respectfully requested that the rejection of claims 21, 40-53 and 70-79 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection of Claim 21 under 35 U.S.C. § 112, first paragraph

Claim 21 is also rejected under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not [sufficiently] described in the specification...." *See*, Paper No. 92004, pages 9-10, item 15. Without acquiescing to the instant rejection, Applicants have herein canceled claim 21 without prejudice or disclaimer, thereby rendering this rejection moot. Applicants reserve the right to pursue claims drawn to all canceled subject matter in one or more divisional or continuation applications.

Conclusion

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425.

Dated: February 15, 2005

Respectfully submitted,

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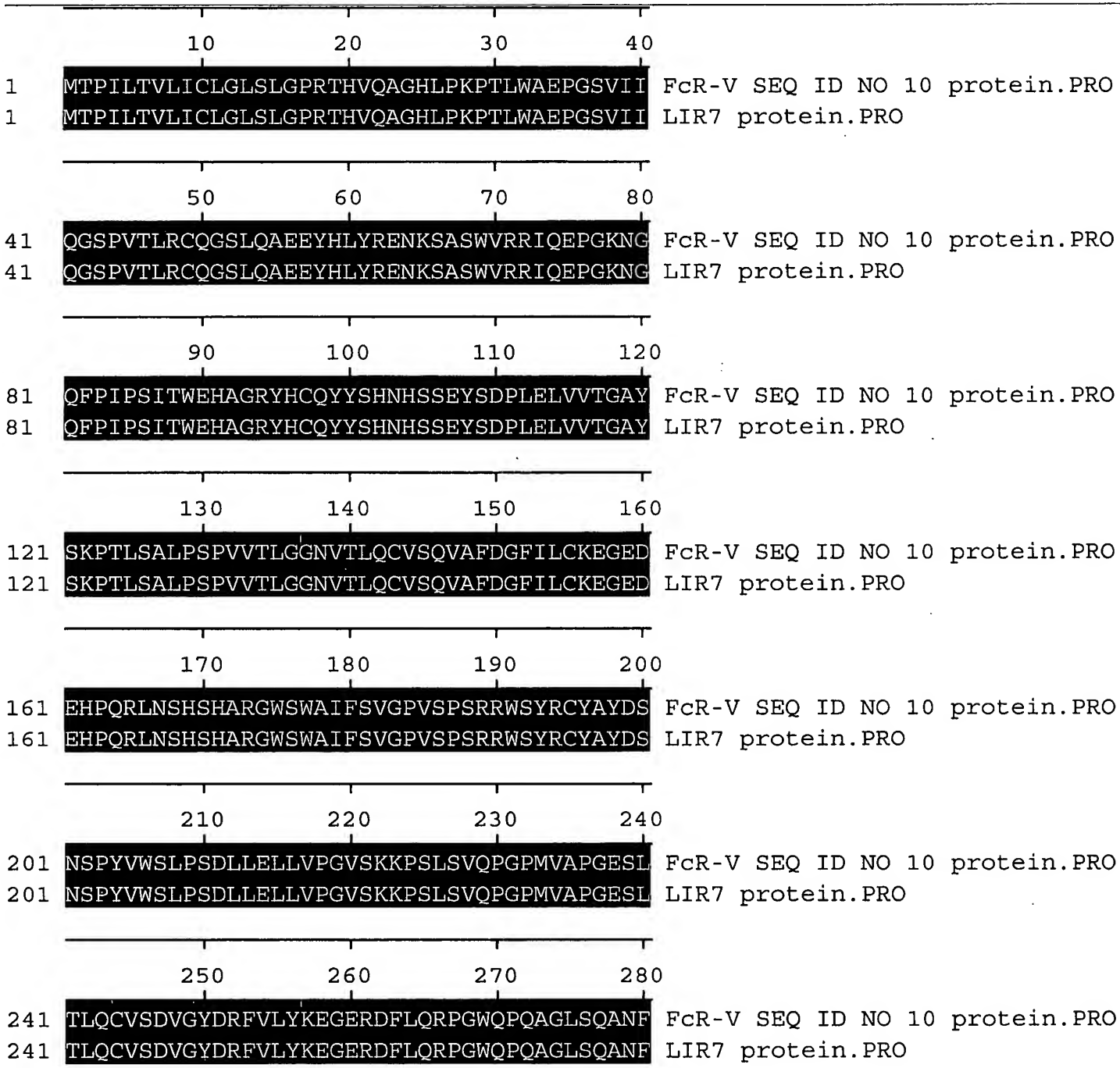

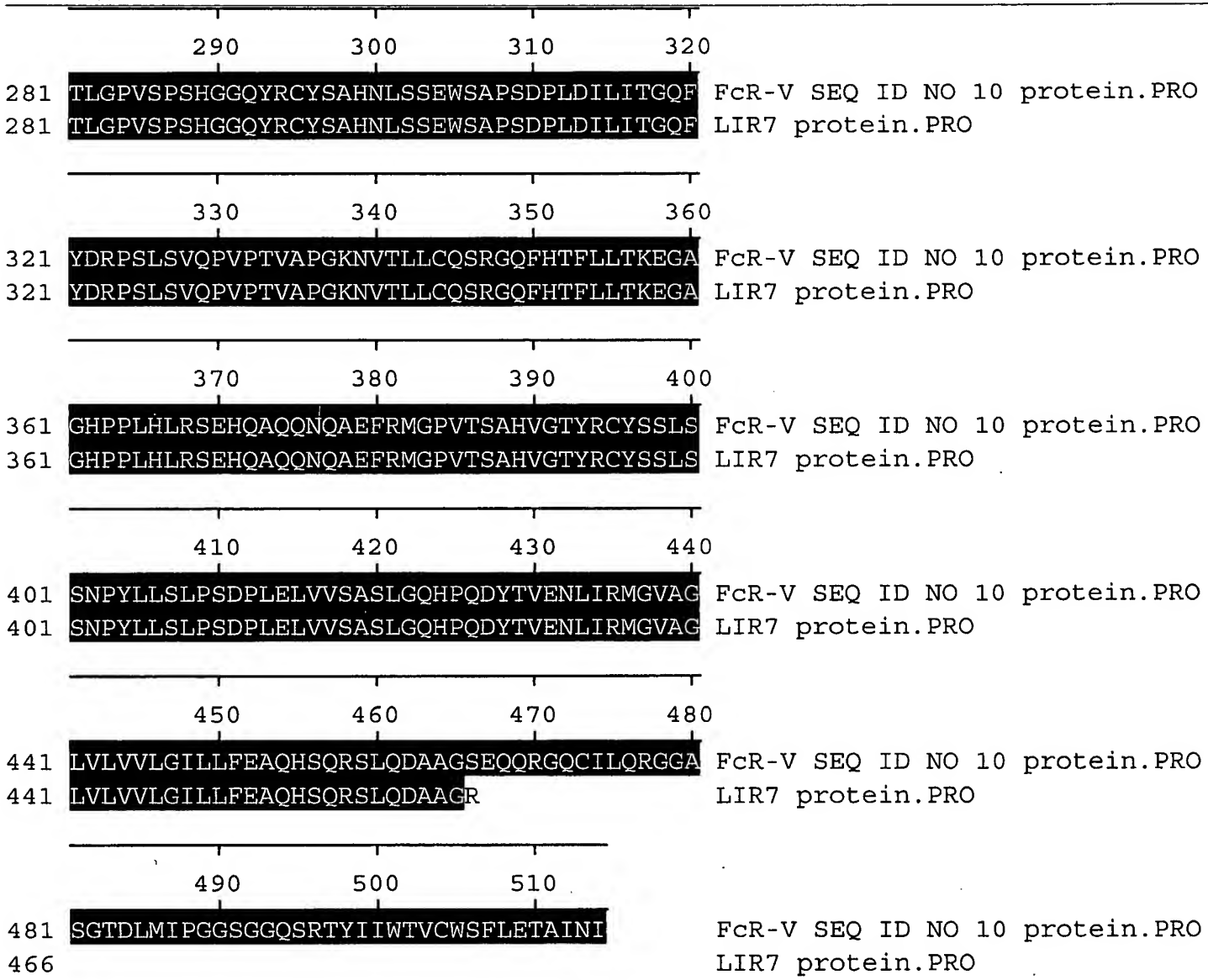

Decoration 'Decoration #1': Shade (with solid black) residues that match FcR-V SEQ ID NO 10 protein.PRO exactly.